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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CRANE, LAWRENCE E

ART UNIT PAPER NUMBER

1623

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/720,907	Applicant(s) PON ET AL.	
	Examiner L. E. Crane	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 10, 2004 (amdt).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9-53,61-106,114-144 and 152-187 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9-53,61-106,114-144 and 152-187 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims **2-8, 54-60, 107-113 and 145-151** have been cancelled, claims **1, 15, 21-22, 25, 30, 37, 42, 53, 67, 71, 73-74, 77, 94, 106, 120, 126, 130, 142-144, 158, 164, 168, 180-181 and 185-187** have been amended, the disclosure has not been further amended, and no new claims have been added as per the amendment filed August 10, 2004. No additional Information Disclosure Statements (IDSs) have been filed as of the date of the Office action.

Claims **1, 9-53, 61-106, 114-144 and 152-187** remain in the case.

Claims **1, 9-53, 61-106, 114-144 and 152-187** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims have not met the written description standard of *Regents of the University of California v. Eli Lilly* (119F.3d 1559 at 1568; 43 USPQ2d 1398 at 1406 (Fed. Cir. 1997)) which MPEP §2163 at page 2100-162, column 1, quotes as follows: "A definition by function alone 'does not suffice' to describe a coding sequence 'because it is only an indication of what the gene does, rather than what it is.'" Applicant continues to rely on generic functional terminology in claim **1** including "'linker moiety'" and "'organic radical'" wherein the disclosure definition thereof does not overcome the functionality of the noted term. See also claims **53, 106, 144 and 185**. Subgeneric terms in claims **2-8** like "at least one carbon atom," "C₁-C₃₀₀ organic moiety," "C₁-C₂₀₀ organic moiety," "C₁-C₁₀₀ organic moiety," "saturated organic moiety," "unsaturated organic moiety," and similar limitations found in claims **9-15 and 27-35** do not overcome this grounds of rejection. See also dependent claims **54-67** and other similarly structured claims.

Applicant's arguments filed August 10, 2004 have been fully considered but they are not deemed to be persuasive.

Applicant argues that the term "linker moiety" is well understood by the ordinary practitioner as the basis for not amending the claims wherein said term is found by replacement of said clearly functional term with a definition adequately supported by a disclosure definition. Examiner notes that the variable "Z" is only defined in a non-functional manner in dependent claims **39-42, 91-94, 127-130 and 165-168**. Because applicant's amendments to date have not effectively addressed the above rejection, examiner suggests that all of the

specific and generic structure-based definitions of "Z" found in the above noted dependent claims be incorporated into each of the independent claims and that the dependent claims be amended to further limit as necessary. Examiner suggests that the same amendment strategy should be applied to all other variables in order to eliminate functional terminology directed to organic chemical structures in independent claims.

Claims 1, 9-53, 61-106, 114-144 and 152-187 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims which depend entirely on functional terminology (all independent claims) is excessive in light of the very limited number of examples in Table 2 of the disclosure.

B. The nature of the invention is directed to linker molecules with utility in solid support oligonucleotide synthesis.

C. The state of the prior art is well developed as revealed by the substantial number of different linker molecules disclosed in the prior art of record.

D. The level of one or ordinary skill is moderate, the only requirement being mastery of the process of solid support derivatization and oligonucleotide synthesis.

E. The level of predictability in the art is fairly high because the organic chemistry being applied is well established and predictable.

F. The amount of direction provided by the inventor is limited to the examples provided in Table 2 and associated examples wherein a limited number of different solid support linkers are shown to be effective in oligonucleotide synthesis.

G. The existence of working examples is very limited as noted above.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive because of the immense and poorly defined scope of the claim language.

Applicant's arguments filed August 10, 2004 have been fully considered but they are not deemed to be persuasive.

Applicant has not removed all of the functional definitions of variables from the independent claims. The above grounds of rejection will remain valid until the above suggested amendments as outlined following the previous grounds of rejection have been made and entered.

Claims **73, 143 and 180-181** are objected to because of the following informalities:

In claim **73** at line 3, there is an extra comma preceding the term "trityl."

In claim **143** at lines 26 and 36, the term "catalysts" appears twice, the first occurrence being followed by specific examples and the second occurrence standing alone. Is this contruction intentional or an unnecessary duplication? See also claim **181** at lines 26 and 35.

In claim **180** the term "acitivating" is a misspelling of the term -- activating --.

Appropriate correction is required.

Claims **1, 9-53, 61-106, 114-144 and 152-187** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required

feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the narrow recitation "Q is an organic moiety," and the dependent claims 9-13 recite "organic moiety comprises" which is the broad statement of the range/limitation. See also claim 18 which recites "Q is an organic moiety" and dependent claim 22 which recites the term "Q comprises," and second dependent claim 30 which recites the term "Q is a C₁-C₁₀₀ organic moiety comprising." See also similar inconsistencies when comparing:

- i) claim 27 ("Q is a C₁-C₁₀₀ organic moiety") with claims 31-35 ("organic moiety comprises");
- ii) claim 53 ("Q is an organic moiety") with claims 61-65 and 82 ("organic moiety comprises at least one");
- iii) claim 76 ("Q is an organic moiety") with claims 83-87 ("organic moiety comprises at least one");
- iv) claim 106 ("Q is an organic moiety") with claims 114-118 ("organic moiety comprises at least one");
- v) claim 144 ("Q is an organic moiety") with claims 152-156 ("organic moiety comprises at least one"); and
- vi) within claim 181, the narrow term "consisting of" at line 3 and the broad term "e.g." at lines 3, 7, 9, 11, 12, 26 and 27.

In claims 142 and 143 a similar problem of varying scope within the same claim is found when comparing the Markush terminology ("selected from the group consisting of") and the parentheticals including the abbreviation "e.g." for the term "for example," which is an open ended term which lacks definable metes and bounds. All of the claims cited in this rejection are as follows: claims 1, 9-13, 18, 22, 30, 27, 31-35, 53, 61-65, 82, 76, 83-87, 106, 114-118, 142-144 and 181.

Applicant's arguments with respect to claims 1-187 have been considered but are deemed to be moot in view of the new grounds of rejection.

Examiner suggests that all of the above noted problems may be resolved by making the independent claims complete in the area of generic chemical formulas; that is to suggest complete definitions of all variables with complete chemical formulas in independent claims, and elimination of reliance on the term "comprising" or its synonyms when referring to variations in the structure of chemical compounds. In effect this would combine all of the

variations of the dependent claims into claim 1 and the dependent claims would be defined to narrow claim 1 as opposed to the present claiming strategy wherein claim 1 is repeatedly expanded in scope by the expansion of functionally defined variables using a --further comprising -- strategy.

In claim 22 at line 7, the term “C₁-C₄₀ ester group” is incomplete for failure to specify the particular type of ester being included (carboxylate, sulfate, phosphate, etc., etc.). Appropriate clarification is respectfully requested. For the same error, see also claims 15, 22, 37, 67, 74, 89, 120 and 158. Examiner notes that the terms “C₁-C₄₀ hydroxy group” and “C₂-C₄₀ acrylate group” also not yet corrected in claim 158.

Applicant's arguments filed August 10, 2004 have been fully considered but they are not deemed to be persuasive.

Applicant's amendments are noted with appreciation. However, the remaining portion of the rejection repeated above has not been addressed. Errors previously pointed out have also not been entirely corrected as noted.

In claims 106, 113-141, 144, 152-179 and 182-187 the disclosed process subject matter fails to include any reference to what chemical reagents are being used to catalyze or otherwise assist in the formation of new chemical bonds, thereby rendering the instant claims incomplete concerning the details to the step or steps required to make same. Even in the claims wherein reactants are listed, (claims 142-143 and 180-181) there is no direction as to whether one or multiple steps are required to execute the claimed processes.

Applicant's arguments filed August 10, 2004 have been fully considered but they are not deemed to be persuasive.

Applicant argues that the claims are “clear and definite” on the basis that any further narrowing would unduly restrict the scope of applicant's claims. Examiner respectfully disagrees and refers applicant to *Brenner v. Manson*, 148 USPQ 689 (S. Ct., 1966) at p. 696, column 1, which stands for the proposition that “[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful completion.” The above amended grounds of rejection have been maintained because applicant has again failed to provide a clear and definite set of process steps in the noted claims wherein all the roles of the necessary and optional chemicals present have been defined by non-functional terminology (e.g. the

functional terms “catalyst” (claim 143), “auxillary nucleophiles” (claim 143) and “activating agent” (claim 141) each beg the question “which have what chemical structures?”). See also the rejections supra under a different part of 35 U.S.C. §112.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 703-872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at **571-272-0661**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

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LECrane:lec
12/08/2004

A handwritten signature in black ink, appearing to be 'J. O. Wilson', written over the date '12/08/2004'.

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600